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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

April 26, 2004

Ref: 2004-DAL-WL-15

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Gary H. Brooks
Chief Executive Officer and President
Positron Corporation
1304 Langham Creek, Ste #300
Houston, Texas 77084-5043

Dear Mr. Brooks:

FDA inspected your establishment in Houston, Texas, on February 17 through 19, 23, and 27, and March 19, 2004. Your firm manufactures the Positron Emission Tomography (PET) diagnostic scanners, such as POSICAM HZ™, POSICAM HZL™, mPower™ PET, which are intended to scan the whole body and multislice for diagnostic imaging. These products are devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection, Mr. William H. Burdette, Quality Systems Manager and Hardware Engineering Director, was issued a Form FDA-483 (copy enclosed) which delineated a number of significant GMP inspectional observations which include, but are not limited to, the following:

1. Failure of the management with executive responsibility to provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal audits [21 CFR 820.20(b)(2)]. For example:

a) You failed to hire new employees or reassign existing employees to ensure that management reviews and internal audits are being conducted at defined intervals [FDA-483 Items 1 – 3];

b) You hired a new Quality System Manager but did not provide this employee with quality system training [FDA-483 Item 7]; and

c) You terminated an employee who handled your firm's customer complaint handling but failed to hire new employees or reassign existing employees to maintain your firm's complaint files. An electronic customer service database was created to document customer complaints, but it was never implemented [FDA-483 Item 6].

2. Failure to conduct and review internal quality audits according to established procedures to assure that your firm's quality system is in compliance with the established quality system requirements [21 CFR 820.22] [FDA-483 Item 1, 2], a similar deviation from the previous inspection in 11/2001. For example:

   a) Only two out of ten quality system areas were audited in 2003. For example, radiation safety, CAPA, inspection and test status, control of non-conforming product, device history records, product identification and traceability, document and data control were not audited; and

   b) Some audit reports were not reviewed in 2002 and 2003. For example, document and data control and human resource report in 2002, and engineering report in 2003.

3. Failure to conduct management reviews at defined intervals according to established procedures [21 CFR 820.22] [FDA-483 Items 3 and 6], a similar deviation from the previous inspection in 11/2001. For example:

   a) Only one out of [redacted] scheduled management reviews was conducted in 2003, and no review was conducted in 2002; and

   b) An electronic customer service database was not implemented to document and evaluate customer complaints as required by your firm's Complaint Handling Procedure (P.O.S. 4.14.03). This deviation was not detected by either management reviews or internal audits.

4. Failure to maintain complaint files for receiving, reviewing, and evaluating complaints by a formally designated unit [21 CFR 820.198(a)] [FDA-483 Item 6], a similar deviation from the previous inspection in 11/2001. For example, one of your firm's employees created a customer service database in order to document all complaints electronically, however, your firm never implemented this database.

5. Failure to analyze sources of quality data to identify existing and potential causes of nonconforming product and other quality problems [21 CFR 820.100(a)(1)] [FDA-483 Item 5], a similar deviation from the previous inspection in 11/2001. For example, your firm is required to conduct [redacted] trend and trigger analyses of quality data per year to support management reviews. However, only one trend and trigger analysis was conducted in 2003.

6. Failure to establish and maintain instructions or procedures for performing and verifying that servicing meets the specified requirements [21 CFR 820.200], a similar deviation from the previous inspection in 11/2001. For example:

   a) Customer service reports do not contain enough information to determine if the reported problems were detected by either the users, resulting in unscheduled service request calls to your firm, or your firm's field engineers during their routine preventive maintenance at the user facilities; and

   b) One out of the eleven customer service reports reviewed, only one report contained the device serial number. See FDA-483 Item 4; and

   c) Several customer service reports revealed a problem with the devices "failing to acquire" or experiencing an "image quality" problem. These service reports did not contain information to indicate or verify if the reported problems were detected during either patient scanning or routine system checks prior to patient scanning, in order to evaluate each event for MDR reportability. See service reports, dated 2/24/03, 8/4/03, 9/15/03.

   d) The above-referenced service reports indicated that an upgrade was needed. There are no records attached or referenced in these service reports or clear descriptions to explain if the upgrade was due to a hardware design problem, a software design problem or other recurring quality problems.

7. Failure to provide employee training to ensure that all personnel are trained to adequately perform their assigned responsibilities [21 CFR 820.25(b)] [FDA-483 Item 7]. For example:

   a) Your firm failed to provide quality system training to an employee manager who is assigned the responsibility to maintain your firm's quality system. This employee indicated that he had no prior experience with the quality assurance and quality system and had not received formal training as a new Quality System Manager; and

   b) Your firm failed to provide update training to employees responsible for handling customer complaints when there had been changes in the complaint handling procedures.

8. Failure to calibrate measuring and test equipment, including mechanical, automated, or electronic inspection and test equipment, to ensure that they are capable of producing valid results [21 CFR 820.72(a)] [FDA-483 Item 9]. For example, all the equipment listed in your firm's Master Calibration List had not been calibrated by their due date in 2004. Your firm stated to our investigator that since your firm was not manufacturing at the time of the inspection, your firm was not required to calibrate the listed measuring equipment. Your firm's rationale is not acceptable since these measuring equipment can be used to verify the results produced during either in-house repairs of electronic/assembly components, design changes or when your firm begins to manufacture new device units.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective actions and preventative action on your quality system.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no applications for premarket approval of Class III devices to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected.

Also, no requests for Certificates for Foreign Governments will be granted until the violations related to the subject devices have been corrected.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Should you need general information about FDA's requirements for medical device manufacturers, you may obtain information on the FDA's website at http://www.fda.gov or by contacting our Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at (800) 638-2041.

Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken, or will take to identify and correct any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address. If you have any questions concerning this matter, you may contact Mr. Ta at (214) 253-5217.

Sincerely,

Michael A. Chappell
Dallas District Director

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